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| EXAMINER | |
|---|---|
| DEAK, LESLIE R | |

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| 3761 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/063,288 | WALLEN ET AL. | |
| | Examiner | Art Unit | |
| | Leslie R. Deak | 3761 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-22 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,17-22 and 46* is/are rejected.

7)☒ Claim(s) *16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8 October 2007 has been entered.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 3, 6-10, and 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,445,630 to Richmond in view of US 3,938,520 to Scislowicz, further in view of US 5,766,211 to Wood.

In the specification and figures, Richmond discloses the device as claimed by applicant. With regard to claims 1 and 9, Richmond discloses a device that is capable of mixing medical fluids comprising ports that may be used as an inlet port, injection port, and outlet port, respectively (see drawing, as annotated by Examiner, in the prior Office action, FIG 6). The device comprises a first duct 180 that extends between the inlet port

and the injection port, and a second duct that extends between the inlet port and the outlet port (see FIG 6). The injection port comprises a hydrophobic, or fluid-proof membrane 182 that is capable of being penetrated by another device (see column 6, lines 18-53). The device further comprises a first portion that houses the inlet port and the injection port and a second portion that houses the outlet port. Richmond illustrates that the portions are separate through the use of diagonal lines, indicating that the portions may be made of different materials.

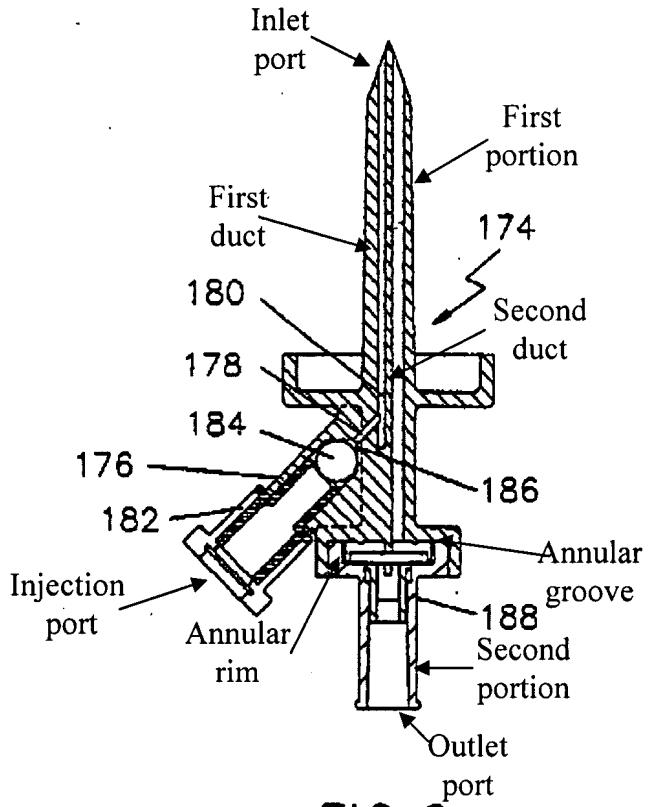


FIG.6.

With regard to applicant's recitation of the friction and snap fit coupling, such couplings are well-known in the art of medical tube connectors, as illustrated by Scislowicz et al. Scislowicz discloses a fluid connector comprising a top transfer section 58, a bottom closure section 70 with a tapering groove 73, and a ridge 76 on the tapered transfer member configured to engage with undercut 75 in the closure portion to form a secure connection between the two parts (see column 6, lines 55-67, FIG 9). Therefore, it would have been obvious to one having ordinary skill in the art at

the time of invention to add a snap fit coupling as disclosed by Scislowicz to the adapter connection disclosed by Richmond in order to provide a secure connection between the parts, as taught by Scislowicz.

Richmond is silent with regard to the materials used to construct the second part of the connector. However, Wood discloses a medical fluid mixing connector that comprises a rigid housing 12 and connecting cylinders 25, 5, and 6, made of an elastic material such as rubber (see Wood, column 5, lines 54-59, column 6, lines 36-45). The elastic material allows for airtight seals between the rigid and non-rigid portions of the device and simplifies connections (see column 6, lines 36-45). It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07. In the instant case, Richmond illustrates that the connector is composed of two pieces, Scislowicz discloses a snap fit connection, and Wood discloses a fluid mixing connector with a rigid portion and an elastomeric portion in order to create airtight seals. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the second portion of the device suggested by Richmond and Scislowicz out of an elastomeric material as disclosed by Wood, in order to create an airtight seal and simplify connections, as taught by Wood (see column 6, lines 36-45).

With regard to claims 2 and 46, Scislowicz illustrates that the first portion comprises an annular, tapering groove (see portion 68, 64 in FIG 9), the second portion comprises an annular tapering rim at 73. The device further comprises a ridge 76 on the

tapered transfer member configured to engage with undercut 75 in the closure portion to form a secure connection between the two parts (see column 6, lines 55-67, FIG 9). The configuration of the tapers and the snap members provide a retention force to retain the members securely connected.

With regard to claim 3, Richmond illustrates that the second portion of the connector comprises a tube section that extends downward from the connection with the first section, wherein the tube comprises a male luer fitting that is capable of receiving a male luer fitting that displaces the valve, such that the male luer fitting corresponds to the piercing member claimed by applicant. With regard to applicant's recitation of a second retention force, such a statement is held by the examiner to be a statement of the function of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, applicant has failed to set forth any structural limitations that create a second retention force, and it appears that the connection between the female and male luer connectors of the Richmond device is retained by some force, meeting the limitations of the claim.

With regard to claim 4, Richmond illustrates a tube-shaped valve member 166/168 (that may be made of the same material as disclosed by Wood, see MPEP 2144.07) that has an increased diameter at the end that abuts valve disc 170 (see FIG 5). The tube shaped element 168 may allow insertion of an infusion line.

With regard to claim 5, the prior art discloses the elements of the claimed device with the exception of the retention forces. The statements drawn to the retention forces between the claimed elements is held by the examiner to be a statement of the function of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, applicant has failed to set forth any structural limitations that generate the claimed retention force of the tube element, and it appears that the tube element disclosed by Richmond is capable of providing a retention force to an inserted device, suggesting the limitations of the claim.

With regard to claims 6 and 15, Richmond discloses that the outlet port is sealed by a barrier or valve disk 170 that may be deformed by a male luer fitting or piercing element, opening a passage within the disk 170 (see column 6, lines 28-42).

With regard to claim 7, Richmond teaches that the connector comprises a polyethylene or other biocompatible plastic material, but is silent as to the method of molding. The claimed phrase "wherein said first portion has been injection molded from a thermoplastic polymer material" is being treated as a product by process limitation; that is, that the connector is made by injection molding. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C.102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113. Thus, even

though Richmond is silent as to the process used to mold the connector, it appears that the product in Richmond would be the same or similar as that claimed; especially since both applicant's product and the prior art product is made of a thermoplastic polymer material (see column 3, lines 50-57).

With regard to claim 8, Richmond specifically discloses that the first portion of the connector may be made of polyethylene (see column 3, lines 51-55).

With regard to claim 10, Richmond illustrates that the inlet port area comprises a spike 10 that is configured for puncturing the membrane 14 of an IV bag 16 (see column 3, lines 59-67).

With regard to claim 14, Richmond discloses that the outlet port is sealed by valve member 170, but fails to disclose that the valve is integral with and made of the same material as the outlet port (see column 6, lines 28-42). It has been held that forming in one piece an article that was formerly been formed in two pieces and put together involves only routine skill in the art. See MPEP 2144.04. Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07. In the instant case, it would have been obvious to a worker in the art to form the barrier disclosed by Richmond integrally with the outlet port, necessarily forming both of the same material, since both modifications are recognized as a matter of obvious design choice.

With regard to claim 17, applicant's language drawn to the function of the base member is held by the examiner to be a statement of the intended use of the base

member. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Richmond discloses that the device comprises flanges 40, 42 (see FIG 1) that are capable of supporting the device when it is in a horizontal position, meeting the limitations of the claims (see column 4, lines 23-33).

With regard to claim 18, Richmond discloses that the device comprises flanges 40, 42 (see FIG 1) that may be gripped by a user, meeting the limitations of the claim.

With regard to claim 19, Richmond discloses that the device may comprise a cap (not shown, see column 4, lines 23-33).

With regard to claim 20, Richmond illustrates that the connector comprises two portions attached to one another, meeting the limitations of the claim.

With regard to claim 21, Richmond discloses that the connector comprises a first portion, second portion, hydrophobic membrane, and a cap or removable hood (see FIG 6, column 3, lines 23-33).

With regard to claim 22, Richmond discloses that the connector may be attached to a drip chamber (see column 1, lines 20-25).

4. Claims 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,445,630 to Richmond in view of in view of US 3,938,520 to Scislowicz, in view of US 5,766,211 to Wood, further in view of US 6,142,446 to Leinsing

In the specification and figures, the prior art suggests the device substantially as claimed by applicant (see rejection above) with the exception of a locking or hook member on the connector that engages with a secondary fluid container. Examiner considers the locking member and hook member to be similar in scope such that they both read on the Leinsing disclosure. Leinsing discloses a medical connector with a body 110 and a cannula 122 that may be inserted into a container 138 of medical fluid (see FIG 18). The body comprises claws 118 that correspond to applicant's locking member or hook member. The claws engage the neck of the secondary container to prevent disengagement of the spike from the container (see column 11, lines 31-57). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the claws as disclosed by Leinsing to the connector as suggested by the prior art in order to maintain a connection between the connector and a secondary fluid container, as taught by Leinsing (see column 11, lines 31-57).

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,445,630 to Richmond in view of in view of US 3,938,520 to Scislowicz, in view of US 5,766,211 to Wood, further in view of US 6,146,362 to Turnbull et al.

In the specification and figures, the prior art suggests the device substantially as claimed by applicant (see rejection above) with the exception of a barb member on the connector that engages the interior surface of a fluid transfer port. Turnbull discloses a fluid transfer device with a fluid transfer spike or key 12 with a retaining ring or barb 50 on the surface of the spike (see column 4, lines 43-65). When the spike is inserted into

a fluid transfer port of an injection port 10, the protrusion engages the interior of the fluid port 10, preventing retraction of the spike 12 from the port (see column 4, lines 43-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a barb member as disclosed by Turnbull to the spiked connector suggested by the prior art in order to prevent disengagement of the spike from a fluid transfer port, as taught by Turnbull (see column 4, lines 43-65).

***Allowable Subject Matter***

6. Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest the device claimed by applicant.

Richmond discloses the apparatus substantially as claimed by applicant, but fails to disclose that port 182 is capable of receiving an injection needle for fluid infusion wherein the needle comprises a fluid transfer device, fluid reservoir, and additional membrane to form a double-bayonet coupling with the disclosed connector. Scislowicz teaches a snap fit coupling, but not a connector with the claimed inlet and outlet ports that are capable of functioning as claimed by applicant in combination with the claimed secondary fluid transfer device. Wood discloses a medical connector with a resilient connector member, but fails to disclose a connector with the claimed inlet and outlet ports that are capable of functioning as claimed by applicant in combination with the

claimed secondary fluid transfer device. Leinsing discloses a medical adapter with fluid inlet and outlet ports, but fails to disclose or suggest the claimed secondary fluid transfer device.

***Response to Arguments***

8. Applicant's amendment and arguments filed 8 October 2007 have been entered and considered.

9. Applicant's arguments with regard to the pending claims have been considered but are moot in view of the new grounds of rejection presented above.

10. Applicant argues that Examiner has not made a *prima facie* case of obviousness over Richmond in view of Wood, since the references fail to teach two components formed of different materials and fail to teach the coupling claimed by applicant.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, the prior art teaches or suggests the structural limitations of the claimed device and provides motivation for their combination. As such, the

combination suggested by examiner is not a result of impermissible hindsight, but rather merely results from the teachings of the cited art.

Applicant argues that Richmond fails to disclose that the components of the device may be made of different materials. However, as noted in the Office Action, Richmond illustrates first portion 188 with one pattern of diagonal stripes and the second portion with a second pattern of diagonal stripes, indicating that the materials may be different. Applicant asserts that the Richmond disclosure teaches that the pieces are likely made from the same material because they are bonded together, which teaches away from the present invention. However, Examiner is not asserting that the Richmond device alone teaches the use of different materials in a multi-piece connector. Examiner is using that particular figure of the Richmond device to show that the pieces are separate, providing the possibility that they may be formed of different materials including a resilient second material, as taught by Wood.

## ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
4 December 2007